DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0878]

Global Harmonization Task Force: Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft'' (draft document). This draft document has been prepared by members of the Global Harmonization Task Force (GHTF), study group 1 on product approval issues and requirements. The draft document is intended to provide information only and represents a harmonized proposal. Elements of the approach set forth in this document may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on this draft document.

DATES: Written comments by January 26, 1999. After the close of the comment period, written comments may be submitted at any time to Kimber C. Richter (address below).

ADDRESSES: Submit written comments on the draft document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web (WWW), submit written requests for single copies on a 3.5'' diskette of the draft document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to this draft document.

FOR FURTHER INFORMATION CONTACT: Kimber C. Richter, Office of Device Evaluation (HFZ–400), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements, as described in an FDA notice on these activities published in the **Federal Register** of October 11, 1995 (60 FR 53078). As part of this effort, FDA has been actively involved since 1992 with GHTF. GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. The purpose of this notice is to seek public comments on a draft document that has been prepared by one of the GHTF study groups.

Study group 1 was formed in January 1993 and was originally tasked with identifying divergence between various regulatory systems. In 1995, the group was asked to propose areas of premarket device regulation and possible guidances or other documents that could lead to harmonization of requirements. As a result of their efforts, this group has developed a draft document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft,'' which suggests a minimum harmonized set of expectations that medical devices worldwide should meet. It is not intended to exclude country-specific requirements or higher standards that already exist. It may be used by governments developing new systems for premarket regulation of devices. This draft document also provides harmonized language for study group 1 to build on as they develop further guidance documents, and may ultimately be adapted in place of country or region-specific language in existing systems.

The draft document is presented for review and comment so that industry and other members of the public may express their views regarding global harmonization of premarket regulation of medical devices.

II. Electronic Access

Persons interested in obtaining a copy of the draft document may also do so using the WWW. CDRH maintains an entry on the WWW for easy access to the Web. Updated on a regular basis, the CDRH home page includes ''Essential Principles for Safety and Performance of Medical Devices on a Global Basis; Final Working Draft,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video-oriented conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

III. Comments

Interested persons may, on or before January 26, 1999, submit to the Dockets Management Branch (address above) written comments regarding the draft document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and with the full title of the document. The draft document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After January 26, 1999, written comments regarding the draft document may be submitted at any time to the contact person (address above).

Dated: October 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0416]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated